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September 11, 2023

Ms. Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1784-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

**RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program**

Dear Administrator Brooks-LaSure,

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. In the paragraphs that follow, we provide feedback on key proposals and policies in the aforementioned rule.

**Conversion Factor (CF)**

We are deeply troubled by ongoing reductions to the Medicare physician fee schedule (PFS) conversion factor, which CMS anticipates will be reduced by \$1.14 and result in a rate of \$32.7476 for CY 2024. This reduction stems from a budget neutrality adjustment of -2.17%, the 0.0 % update adjustment factor required under the Medicare Access and CHIP Reauthorization Act (MACRA), and a 1.25% payment update provided under the Consolidation Appropriations Act, 2023 (CAA, 2023).

While CMS must implement the law as written, we are increasingly concerned about year-after-year pay cuts that negatively impact A/I practices and threaten access to care. Even more frustrating is that almost every other provider type in Medicare (e.g., acute care hospitals, hospital outpatient departments, ambulatory surgery centers) will receive a substantial increase in their base payment rate for 2024.

As you know, physicians face the same challenges with high inflation as all other Medicare providers, including recruiting and retaining clinical and administrative staff and purchasing equipment and supplies. Without a more stable payment system, many practices may limit the number of new Medicare patients they are willing to see, with some fully opting-out of Medicare. Others are vertically integrating with hospitals and healthcare systems, or closing their practices altogether to seek employment elsewhere.

***CMS may have limited authority to address some of the underlying issues that plague the physician payment system, but it can – and must – work with the Congress on long-term solutions to these challenges and avoid a major fallout.***

### Practice Expense Data Collection

We appreciate that CMS has paused the use of other sources of cost data for use in the physician payment system until the efforts by the American Medical Association (AMA) to collect practice cost data from physician offices is complete. Using the most current and appropriate set of data, particularly for the Medicare Economic Index (MEI) is critical should Congress consider the MEI as an inflation proxy under a revised Medicare physician payment construct.

As CMS continues to improve its approach for collecting practice expense (PE) data, ***we also ask that CMS establish a more consistent and regular approach for direct PEs, as well as indirect PEs.*** Our practices that deliver physician-administered drugs in the office continue to be harmed by CMS' clinical labor pricing updates that reduced drug administration services. These cuts would not be as drastic had CMS not waited 20 years to revise the clinical labor inputs.

### Evaluation and Management (E/M)

#### *Complexity Add-on Code*

Now that the Congressional moratorium is about to lapse, CMS proposes to begin paying for a "complexity add-on code" (HCPCS code G2211) that it finalized in CY 2021 PFS rulemaking. Under CMS' revised utilization assumptions, the Agency estimates that the code would be used on about 38% of all office and outpatient E/Ms in 2024, and would result in a -2.0% budget neutrality adjustment to the CY 2024 CF. The projected overall impact on Allergy/Immunology is -1.0%.

While the code descriptor remains unchanged from its finalized version, CMS proposes a new "billing rule" that would prevent use of the add-on code on an E/M that carries a ~25 modifier. Noteworthy, CMS states that the add-on code is not intended for use by a "*professional whose relationship with the patient is of a discrete, routine, or time-limited nature; such as, but not limited to, . . . counseling related to seasonal allergies.*"

***AAAAI is deeply concerned about the impact of this payment policy on our specialty, which is -1.0% based on CMS' impact tables.*** First and foremost, the likelihood that A/I clinicians could adopt this add-on code in practice is extremely low considering the majority of our patient base for most of our practices largely falls outside Medicare. While the add-on code may have a positive financial impact on some A/I practices that do see a higher percentage of Medicare patients, that increase is unlikely to "make up the difference" stemming from the reduction in the conversion factor. More importantly, because Medicare's payment rates are the basis for which most private plans set their contracted rates, our payments will be further reduced, even though we won't be able to use this CMS-established code with the majority of our primary patient population to help us overcome the conversion factor cut.

In addition, if our practices adopted this add-on code for our Medicare population, we are also concerned about differentiating the time and effort described by this code and the associated E/M service, which is relatively unclear from the rule. CMS does not explain how practices would count the time and effort for the add-on code and the associated E/M to avoid duplicate payments for the same work, making our practices vulnerable to audits and payment recoupments if errors are made.

Finally, we are concerned that CMS' utilization estimates are overstated, causing the budget-neutrality impact to be more severe than warranted. As highlighted by the AMA's Relative Value Scale Update Committee (RUC), the American College of Physicians states that the utilization should be less than 10% of all office visit codes.<sup>1</sup> It also stands to reason that CMS could exempt the add-on code from budget-neutrality requirements, similar to what it has done with other agency-established services, over the years.

Considering the above, ***we urge CMS to either exempt the complexity add-on code from budget-neutral adjustments and provide clear coding and billing guidance, or eliminate the complexity add-on code altogether.***

### Telehealth

Telehealth remains an important tool for the delivery of A/I care, even absent the COVID-19 public health emergency (PHE). With that in mind, we appreciate CMS' thoughtful policies to maintain access to robust telehealth services for beneficiaries, including implementation requirements set for in the *Consolidated Appropriations Act, 2023*. AAAAAI also appreciates that the telephone E/M services (CPT codes 99441-99443) are deemed "telehealth services" and will remain actively priced through CY 2024. ***We urge CMS to continue assigning active payment status to the telephone E/M services.***

We also appreciate that CMS will continue defining direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024. Our practices have asked for additional clarification on "virtual presence" given perceived discrepancies between what is stated in the [April 6, 2020 Interim Final Rule with Comment \(IFC\)](#) establishing this policy, and later [Frequently Asked Questions \(FAQs\)](#). Specifically, practices have asked if – to meet the direct supervision requirement using real-time audio-visual technology – the physician needs to be ***constantly present*** on the real-time audio-visual technology during the entirety of the provision of an "incident to" service by their clinical staff? The IFC is a bit vague, but the FAQ document, speaking in the context of physical and occupational therapy (PT/OT), states the following:

*"6. Question: Does the revised definition of direct supervision that includes virtual presence as defined at 42 CFR 410.32(b)(3)(ii) apply to physical therapists (PTs) and occupational therapists (OTs) in Private Practice who are required to provide direct supervision of their therapy assistants – physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) – when they furnish services?"*

*Answer: The revised definition of direct supervision at 42 CFR 410.32(b)(3)(ii) allows virtual presence of the supervising professional through the use of interactive telecommunications technology for the duration of the Public Health Emergency (PHE). PTs and OTs in private practice must directly supervise their PTAs and OTAs,*

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<sup>1</sup> <https://acpinternist.org/archives/2023/05/the-case-for-g2211-medicare-visit-complexity-code.htm>

respectively, and may do so through their virtual presence whether they are providing supervision of PTAs/OTAs in the office, in the beneficiary's home, or when therapy assistants are furnishing therapy services via telehealth. **As direct supervision requires the PT's/OT's immediate availability, but not their constant presence in the room during the service, the PT/OT does not need to be in contact 100% of the time, but they need to be ready to provide the virtual presence whenever it's needed. [emphasis added]**

New: 10/6/21”

We would appreciate CMS providing additional clarity in the context of other clinician services.

We also support the Agency's proposal to improve the process by which services are added to the Medicare Telehealth List, consolidating services into either “permanent” (Category I) or “provisional” (Category II) categories. ***CMS should finalize this policy.***

***Finally, we encourage CMS to continue working with Congress to remove originating site requirements and geographic restrictions on a permanent basis, and to encourage states to adopt the Interstate Medical Licensure Compact (IMLC) to improve access to care across state lines.***

#### **Inflation Reduction Act Implementation**

##### ***Discarded Drug Rebates***

Currently, CMS requires practices to report either a JW or JZ modifier on their Part B claims if there are, or are not, discarded drugs amounts, following delivery of a physician-administered medication, respectively. These modifiers help CMS facilitate provisions in the *Infrastructure Investment and Jobs Act* that require manufacturers to provide a refund to CMS for discarded amounts from certain single-dose container or single-use package drugs. In this rule, CMS proposes to require that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier.

As stated previously, ***AAAAI welcomes the opportunity to collaborate with CMS on educational resources to ensure these modifiers are appropriately reported so that CMS can calculate the amount owed by drug manufacturers.***

#### **RFI on Complex Drug Administration and SAD Exclusion List**

***AAAAI urges CMS to direct its Medicare Administrative Contractors (MACs) to rescind all “Billing and Coding: Complex Drug Administration” local coverage articles (LCAs).*** These LCAs “educate” our practices to “down code” their drug administration services from “complex” to “therapeutic,” which is inappropriate based on the time and resources required to deliver the service, not to mention inconsistent with American Medical Association (AMA) CPT descriptions and associated coding guidance.

In addition, ***CMS must make the substance of its August 12, 2022 Technical Direction Letter (TDL) that directs the MACs to pay drug administration service claims using the “complex” drug administration codes, publicly available.***

Separately, our practices and patients faced a major challenge last year when MACs placed tezepelumab-ekko (Tezspire) on the Self-Administered Drug (SAD) Exclusion List, even though the package label indicated that the medication was “intended for administration by a healthcare

provider.” At the time, the manufacturer had provided no instruction for the medication to be administered by the patient.

We appreciate that CMS was expeditious in correcting this issue, but we remain concerned with the criteria the MACs are using to determine if a drug is self-administered or not, given our experience. For example, the MACs have failed to provide a reliable data source that leads them to determine whether a medication is “usually” administered “by the patient.”

**AAAAI contends that major revisions to the criteria used to determine whether a drug should be added to the SAD Exclusion List are necessary, including increased transparency in how such determinations are made.**

Through a multi-provider coalition effort, we have separately provided additional feedback on this RFI, including solutions to address the underlying challenges.

### Vaccine Administration

AAAAI appreciates CMS proposal to maintain the in-home additional payment for COVID vaccine administration under the Part B preventive vaccine benefit, and to extend that additional payment to administration of the other three preventive vaccines included in the Part B preventive vaccine benefit (pneumococcal, influenza, and hepatitis B). **We urge CMS to finalize this policy.**

### The Role of Specialists in Shared Savings Program (SSP) Accountable Care Organizations (ACOs)

For years, AAAAI has raised concerns about the challenges A/I clinicians face in joining Medicare SSP ACOs. We appreciate CMS’ acknowledgment of this in the below passage from its discussion on Individual [Qualifying Participant] Determination in this proposed rule.

*“We have received reports from Advanced APM participants and specialty societies that some APM Entities have taken steps to exclude from their APM Entity groups (and consequently from their Participation Lists) eligible clinicians who furnish proportionally fewer services that lead to the attribution of patients or payment amounts for purposes of calculating Threshold Scores for APM Entity-level QP determinations. For reasons stated above, this action typically would lead to the exclusion of certain specialists from the APM Entity. There are important reasons that it is not beneficial for an APM Entity to exclude specialists and other eligible clinicians who furnish relatively fewer services that lead to attribution. In both the Medicare Shared Savings Program and in models tested by the Innovation Center that meet the criteria to be Advanced APMs, CMS seeks to promote patient-centered care that is integrated across the continuum of care. The inclusion of specialists in APM Entities is essential for achieving this goal. For example, a comprehensive network that includes a range of specialists is central to the success of an ACO in the Medicare Shared Savings Program for its intended purpose in patient-centered care that coordinates items and services for Medicare FFS beneficiaries, a key aim of value-based care and practice transformation.”*

We agree with CMS that specialists, particularly A/I clinicians, have a valuable role in the SSP and other Medicare ACO models. Allergy/Immunology clinicians lead in the diagnosis, treatment and ongoing management of asthma, allergic and immunologic conditions. Allergy/Immunology clinicians also have expertise in a multitude of other key conditions and disease processes, including preventative and concurrent therapies that would significantly enhance diagnosis,

treatment and ongoing management for key conditions generally provided by other medical specialists. Examples include perioperative reactions; antibiotic allergies; metal allergies; adverse food reactions; aspirin sensitivity; chemotherapy hypersensitivity; acute and chronic sinus disease; and, primary immunodeficiency. As participants in an ACO, A/I clinicians would enhance care quality and reduce resource use in these and other key areas.

We appreciate CMS' proposals to better account for specialty care in the SSP, however, nothing prevents ACOs from blocking specialists' participation. Like most health plans, ACOs should be required to maintain adequate "participant" lists, even if assigned beneficiaries have the ability to seek care outside the ACO's "network." ***We urge CMS to establish additional requirements for ACOs consistent with this sentiment.***

Further, ***we ask that CMS publicly release data on the participation rates of A/I professionals in ACOs, similar to what it provided in rulemaking when the Quality Payment Program (QPP) was first implemented.***

Finally, ***CMS must establish additional pathways for A/I professionals to meaningfully engage in the ACO program, especially given the challenges they face participating in the Merit-Based Incentive Payment System (MIPS).***

#### Merit-Based Incentive Payment System (MIPS)

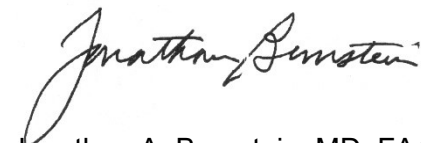
Each year, the Merit-Based Incentive Payment System (MIPS) undergoes hefty revisions that force practices to pivot and change course to meaningfully participate, earn an incentive, and most importantly, avoid a penalty. Participation is an even greater challenge for smaller A/I practices that have less resources available to support engagement. We, along with the rest of the medical community, have continuously shared that the administrative burden to keep up with the ever changing MIPS program requirements is extremely high, and we continue to question the value of the program on our practices ability to deliver quality care. CMS implemented the MIPS Value Pathways (MVPs) in CY 2023 with the goal of streamlining reporting and increasing clinical relevance. While we appreciate the effort, the program still retains aspects of the current program that clinicians find most frustrating (e.g., flawed scoring policies, limited specialty-focused measures, EHR barriers, inappropriate cost measures).

***We urge CMS to study the MIPS program's impact on the quality and experience of care, how it has reduced program and beneficiary costs, and its role in positive health outcomes in key populations, including the underserved, and use those findings to modify the program.***

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at [sheitzig@aaaai.org](mailto:sheitzig@aaaai.org) or (414) 272-6071.

Sincerely,



Jonathan A. Bernstein, MD, FAAAAI  
President, American Academy of Allergy, Asthma & Immunology